ITM and clinical trials

Tackling unmet medical needs with the help of the Clinical Trials Unit

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Dit is de omschrijving

In early January, a phase 3 trial of the COVID-19 vaccine developed by Johnson & Johnson started at ITM. Apart from this trial, clinical studies are being set up and carried out all over the world constantly. ITM has longstanding experience in preparing and coordinating both clinical trials (with medicines or health products) and other trials involving healthy volunteers or patients. So what exactly does this job entail?

ITM's Clinical Trials Unit supports researchers who want to set up and carry out a clinical trial, whether or not in consultation with (inter)national partners. To this end, they have experts in various fields: data management, project management and statistics. They take on an independent role, separate from the researcher and the clinical team. By observing international guidelines on "Good Clinical Practices" (GCP) as well as Belgian and European legislation, they ensure that studies are conducted according to the highest possible quality standards, with respect for the rights of the study participants and with a view to obtaining qualitative study results. The CTU has noticed a recent increase in the volume and variety of studies. In 2020, fifteen studies were ongoing and nine were in preparation. In addition, there are a number of projects in the pipeline awaiting approval. Of the CTU-supported studies several are related to COVID-19, such as COVIDATA, IMSEQ, Ensemble-2, Anticov and Africover. Other studies that are ongoing or planned this year involve rabies, gonorrhoea, tuberculosis, leishmaniasis, leprosy, schistosomiasis, fever syndrome and blood infection.

Commercial and non-commercial studies

We speak of a clinical trial when the safety or effectiveness of a new or existing medicine is examined. During his career, Yven van Herrewege, head of ITM's CTU, became acquainted with both commercial and non-commercial (academic) studies. "The main difference between commercial and non-commercial or academic studies lies in the purpose. Whereas commercial trials go through a development process with the aim of bringing a new medicine on the market, such as a vaccine against COVID-19, researchers in academic trials usually want to create added value on the basis of already approved, existing medicine. To do so, they look for 'unmet medical needs'."

For example, the CTU worked with infectious disease expert Dr Emmanuel Bottieau to evaluate an alternative treatment for the parasitic infection schistosomiasis. A study in Senegal compares the standard treatment for schistosomiasis with an antimalarial drug that is already on the market and for which there are indications that it could also work against other infectious diseases such as schistosomiasis. The study put the two medicines side by side, administering the classical product to one half of the patients and the antimalarial drug to the other half, with the aim of comparing the effectiveness of both treatments.

Another example is the rabies vaccine. Before leaving for an area where there's risk of rabies infection, you must follow a certain vaccination schedule. The CTU has already supported several studies of rabies expert Dr Patrick Soentjes in which they evaluated whether existing vaccination schemes can be adapted by shortening them or by adjusting the doses. Classically, the vaccine is injected intramuscularly. Would a smaller dose administered intradermally also be effective? This is also relevant, because it's cheaper and logistically simpler to use fewer doses.

Good clinical practice (GCP)

In terms of legislation and GCP guidelines, academic and commercial trials are identical; no distinction is made as to who conducts the clinical study. Good Clinical Practice is an international ethical and scientific quality standard on how to plan, conduct and report a study on humans. On the other hand, there is also Belgian and international legislation (in which working according to GCP guidelines is included as a requirement) which ITM, as organiser of

clinical trials, has to follow. The role of the CTU is therefore to provide independent support based on the GCP guidelines and legislation, in the set-up, conduct and reporting of clinical studies by ITM researchers.

Despite the difference, the two types of studies are not entirely separate. Academic studies complement the commercial studies. Because once commercials studies have gone through a development programme, academic studies often follow to look into the other options, as in the examples above. It is therefore a misconception that there are no clinical studies on medicines that are already on the market. The CTU primarily supports academic studies, but can also supervise the commercial counterpart, as it is currently the case for the COVID-19 vaccination study of Johnson & Johnson, where two study coordinators and a data manager are providing support to the clinical team of ITM.

Lastly, capacity building and training are two other important components of the CTU. At the Institute, this takes the shape of protocol and GCP training. But also outside ITM, at partner institutes such as the Belgian Health Care Knowledge Centre, the IPK in Havana and the INRB in Kinshasa, CTU provides training. An example of capacity building is CREDO, a large-scale project to assist Congolese scientists in their research into new and re-emerging epidemics and to learn from each other from the COVID-19 approach.